

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael R.S. Hill et al. Examiner: Frances P. Oropeza

Serial No. 10/039,307 Group Art: 3766

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Confirmation No.: 2140

Title: CLOSED LOOP NEUROMODULATION FOR PREVENTION AND
TREATMENT OF CARDIAC CONDITIONS

APPEAL BRIEF

Mail Stop Appeal Brief
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is filed pursuant to in response to the Notice of Appeal filed September 23, 2009. A two month extension of time to respond is requested.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

Request for Extension of Time

Under the provisions of 37 CFR §1.136(a), Applicant petitions to extend the period for filing a reply in the above-identified application as follows:

- ☐ 37 CFR § 1.17(a)(1)-Extension within first month.
- ☒ 37 CFR § 1.17(a)(2)-Extension within second month.
- ☐ 37 CFR § 1.17(a)(3)-Extension within third month.

Fees Associated with Extension

Payment of the fee for any requested extension is authorized in the above fee section.

I. Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

II. Related appeals and interferences

None.

III. Status of the claims

Claims 17 – 20, 41 – 47 and 54 - 61 are pending.

Claims 17 – 20 and 41 – 47 are all rejected.

Claims 54 – 61 stand withdrawn due to a constructive election requirement.

The rejection of claims 17 – 20 and 41 – 47 is hereby appealed.

IV. Status of amendments

The Amendment mailed August 21, 2009 has been entered. No amendments were made to the claims at that time.

The Appendix of Claims reflects the claims as finally rejected.

V. Summary of claimed subject matter

Claim 17 is the only independent claim appealed. Patentability of the dependent claims is not separately argued.

Claim 17 sets forth an apparatus for treating a patient to improve cardiac performance and efficiency of the patient's heart.

The apparatus comprises at least one electrode adapted to be located in a region associated with nervous tissue in a patient. The electrodes 108 are illustrated in Figures 1 A, B and C. Various locations associated with nervous tissue are described at page 5, line 9 to page 6, line 2

The apparatus comprises means for monitoring one or more physiologic parameters of the patient. The receiver circuit 202, (Figure 2) as discussed at page 11, line 29 to page 12, line 2 receives signals indicative of physiological parameters from the sensors 110, 111 (Figures 1A – 1C) as discussed at page 9, line 29 to page 10, line 30.

The apparatus comprises means for automatically applying electrical stimulation via the at least one electrode to improve balance of a neuro-endocrinological system of the patient in response to the one or more physiologic parameters of the patient. The electrical stimulation is provided to the electrodes by driver circuit 200 (Figure 2), under control of processor 204 (Figure 2). The processor controls the delivery of stimulation automatically as illustrated in Figure 3 and described at 12, line 14 to page 13, line 22.

The apparatus means for delivering a pacing therapy to the patient's heart of a type that improves cardiac output, wherein said pacing therapy consists of a cardiac resynchronization therapy. The pacing therapy is delivered by pacing circuit 109 (Figure 2). The delivered pacing therapy may be a cardiac resynchronization therapy, as described at page 7, lines 3 – 14.

The apparatus comprises means for adjusting the electrical stimulation applied during delivery of the pacing therapy responsive to the one or more physiological parameters of the patient as monitored during delivery of the pacing therapy. The processor 204 adjusts the parameters of the delivered pacing therapy responsive to parameters monitored during delivery of the therapy as illustrated in the flow-charts of Figures 4 and 5 and as discussed at page 15, line 8 to page 16, line 12.

VI. Grounds of rejection to be reviewed on appeal

1. Claims 17, 18, 20, 41, 42, 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '428 patent to Obel et al. (Obel) and the '326 patent to Collins (Collins) in view of the '898 patent to Limousin (Limousin).

2. Claim 19 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Obel, Collins and Limousin as applied to Claim 17 and further in view of the '187 patent to Adams (Adams).

3. Claims 43 – 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Obel, Collins and Limousin in view of the '277 patent to Sjostrand, et al. (Sjostrand).

Applicant respectfully traverses all rejections.

VII. Argument

1. Claims 17, 18, 20, 41, 42, 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '428 patent to Obel et al. (Obel) and the '326 patent to Collins (Collins) in view of the '898 patent to Limousin (Limousin).

Applicant respectfully traverses this rejection.

The claims are limited to a device that adjusts electrical nerve stimulation delivered during a delivered cardiac pacing therapy responsive to physiological parameters monitored during the delivery of the cardiac pacing therapy. Obel's device simply does not do this.

The final paragraph of Independent claim 17, for example, requires "means for adjusting the electrical stimulation applied during delivery of the pacing therapy responsive to the one or more physiological parameters of the patient as monitored during delivery of the pacing therapy" (emphasis added). "The pacing therapy" refers back to the pacing therapy being delivered as set forth previously in the claim, and so both references to it in the final paragraph must be interpreted as referring to delivery of the same pacing therapy. The word "the" could be replaced with the word "said", without changing the meaning of the claims.

Claim 17 thus cannot be properly read as referring to adjustment of parameters after delivery of a prior pacing therapy and prior to the next "delivery of the pacing therapy", as the device disclosed in the cited Obel reference does. The rejection violates the rules of claim interpretation and is also precisely contrary to the usage of the language in the claim in the specification of the application. As such, the Examiner's interpretation of the claim language cannot be considered to be "reasonable". further, the claim element in question is a "means plus function" element, and Obel works contrary to the operation of this element as described in the claims and discussed above.

If terms in a patent claim are arguably capable of contrary or inconsistent interpretations, they must be given the same interpretation as used in the specification. The law does not require that patent claims use only terms which are not susceptible to arguably different meanings. Most English words have multiple possible meanings, and interpreting the words to have meanings contrary to their usage in the application is not

permissible either before or after issuance of the patent. This is particularly so in the case of “means plus function” elements.

The nerve stimulation therapies of Obel are delivered according to pre-programmed parameters which are not varied during their delivery, and thus not varied during delivery of the associated cardiac pacing therapy. Correspondingly, the parameters are not varied during previous delivered nerve or pacing therapies either. The nerve stimulation parameters are adjusted only between deliveries of the therapies. As such, Obel functions directly contrary to the limitations of claim 17 and all other claims still pending. .

Because Obel does not include the teaching it is cited for and in fact teaches the contrary, the rejections of the claims over Obel are respectfully asserted to be clearly erroneous. The cited Collins and Limousin references are not cited as containing this missing teaching and do not in fact contain this missing teaching. Withdrawal of the rejections of claims 17, 18, 20, 41, 42, 46 and 47 is thus respectfully requested.

The cited text in the Abstract of Obel does not contradict the above assertions. The cited text is directed toward initiation of the therapy, which of necessity must occur responsive to parameters sensed prior to initiation of the therapy. As described in detail in the specification, pacing is initiated concurrent with the nerve stimulation therapy in Obel. The cited text thus actually proves the correctness of applicants’ assertions.

The Adams and Sjostrand references cited against claims 19 and 43 – 45 are not cited as making up for the deficiencies of Obel as discussed above with regard to claim 17 and in fact do not make up for these deficiencies. Withdrawal of the rejections of claims 19 and 43 – 45 is thus respectfully requested

Accordingly, applicant respectfully asserts that claim 17 as amended and all claims dependant thereon are patentable over the cited references. Withdrawal of the

rejection under 35 U.S.C. § 103(a) of all previously submitted claims is respectfully requested.

2. Claim 19 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Obel, Collins and Limousin as applied to Claim 17 and further in view of the '187 patent to Adams (Adams).

Applicant respectfully traverses this rejection.

Adams does not overcome the deficiencies of Obel, Collins and Limousin as discussed above in conjunction with claim 17. Withdrawal of this rejection under 35 U.S.C. § 103(a) is also respectfully requested.

3. Claims 43 – 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Obel, Collins and Limousin in view of the '277 patent to Sjostrand, et al. (Sjostrand).

Applicant respectfully traverses this rejection.

Sjostrand does not overcome the deficiencies of Obel, Collins and Limousin as discussed above in conjunction with claim 17. Withdrawal of this rejection under 35 U.S.C. § 103(a) is also respectfully requested.

Because no previously submitted claims have been amended, It is respectfully asserted that any new rejection of the previously submitted claims, including any rejection based on a new interpretation of the Obel, Collins, Limousin, Adams and/or Sjostrand references must take the form of a non-final rejection.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: January 20, 2010

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XIII. Appendix – Claims

1-16. (Canceled)

17. An apparatus for treating a patient to improve cardiac performance and efficiency of the patient's heart, the apparatus comprising:

at least one electrode adapted to be located in a region associated with nervous tissue in a patient;

means for monitoring one or more physiologic parameters of the patient;

means for automatically applying electrical stimulation via the at least one electrode to improve balance of a neuro-endocrinological system of the patient in response to the one or more physiologic parameters of the patient; and

means for delivering a pacing therapy to the patient's heart of a type that improves cardiac output, wherein said pacing therapy consists of a cardiac resynchronization therapy; and

means for adjusting the electrical stimulation applied during delivery of the pacing therapy responsive to the one or more physiological parameters of the patient as monitored during delivery of the pacing therapy.

18. The apparatus of claim 17, wherein the at least one electrode further comprises at least one implanted electrode adapted to be located adjacent a patient's spine.

19. The apparatus of claim 17, wherein the at least one electrode is adapted to be located external to and in direct contact with a portion of skin of the patient's.

20. The apparatus of claim 17, wherein the at least one electrode is adapted to be located in a subcutaneous space of the patient's body.

21 - 40. (Canceled)

41. The apparatus of claim 17 wherein delivery of the pacing therapy comprises altering a previously delivered pacing therapy in conjunction with applying the electrical stimulation.

42. The apparatus of claim 17 wherein delivery of the pacing therapy comprises initiating delivery of the pacing therapy in conjunction with applying the electrical stimulation.

43. The apparatus of claim 17 wherein the monitoring means comprises a pressure sensor.

44. The apparatus of claim 17 wherein the monitoring means comprises a pressure sensor adapted for a cardiac location.

45. The apparatus of claim 44 wherein the monitoring means comprises means for determining the patient's diastolic pressure.

46. The apparatus of claim 17 wherein the monitoring means comprises means for sensing heart rate.

47. The apparatus of claim 46 wherein the monitoring means comprises means for sensing heart rate variability.

48 - 53. (Cancelled)

54. (Withdrawn) An apparatus for treating a patient to improve cardiac performance and efficiency of the patient's heart, the apparatus comprising:
at least one electrode adapted to be located in a region associated with nervous tissue in a patient;
means for monitoring one or more physiologic parameters of the patient;

means for automatically applying electrical stimulation via the at least one electrode to improve balance of a neuro-endocrinological system of the patient in response to the one or more physiologic parameters of the patient; and

means for delivering a pacing therapy to the patient's heart of a type that improves cardiac output, wherein said pacing therapy consists of a cardiac resynchronization therapy; and

means for adjusting the parameters of electrical stimulation applied during delivery of the electrical stimulation responsive to the one or more physiological parameters of the patient as monitored during contemporaneous delivery of the pacing therapy.

55. (Withdrawn) The apparatus of claim 54 wherein delivery of the pacing therapy comprises altering a previously delivered pacing therapy in conjunction with applying the electrical stimulation.

56. (Withdrawn) The apparatus of claim 54 wherein delivery of the pacing therapy comprises initiating delivery of the pacing therapy in conjunction with applying the electrical stimulation.

57. (Withdrawn) The apparatus of claim 54 wherein the monitoring means comprises a pressure sensor.

58. (Withdrawn) The apparatus of claim 57 wherein the monitoring means comprises a pressure sensor adapted for a cardiac location.

59. (Withdrawn) The apparatus of claim 58 wherein the monitoring means comprises means for determining the patient's diastolic pressure.

60. (Withdrawn) The apparatus of claim 54 wherein the monitoring means comprises means for sensing heart rate.

61. (Withdrawn) The apparatus of claim 60 wherein the monitoring means comprises means for sensing heart rate variability.

IX. Appendix – Evidence

None

X. Appendix – Other proceedings

None